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RVD2007-04

Re-evaluation Decision

S-methoprene

(publié aussi en français)

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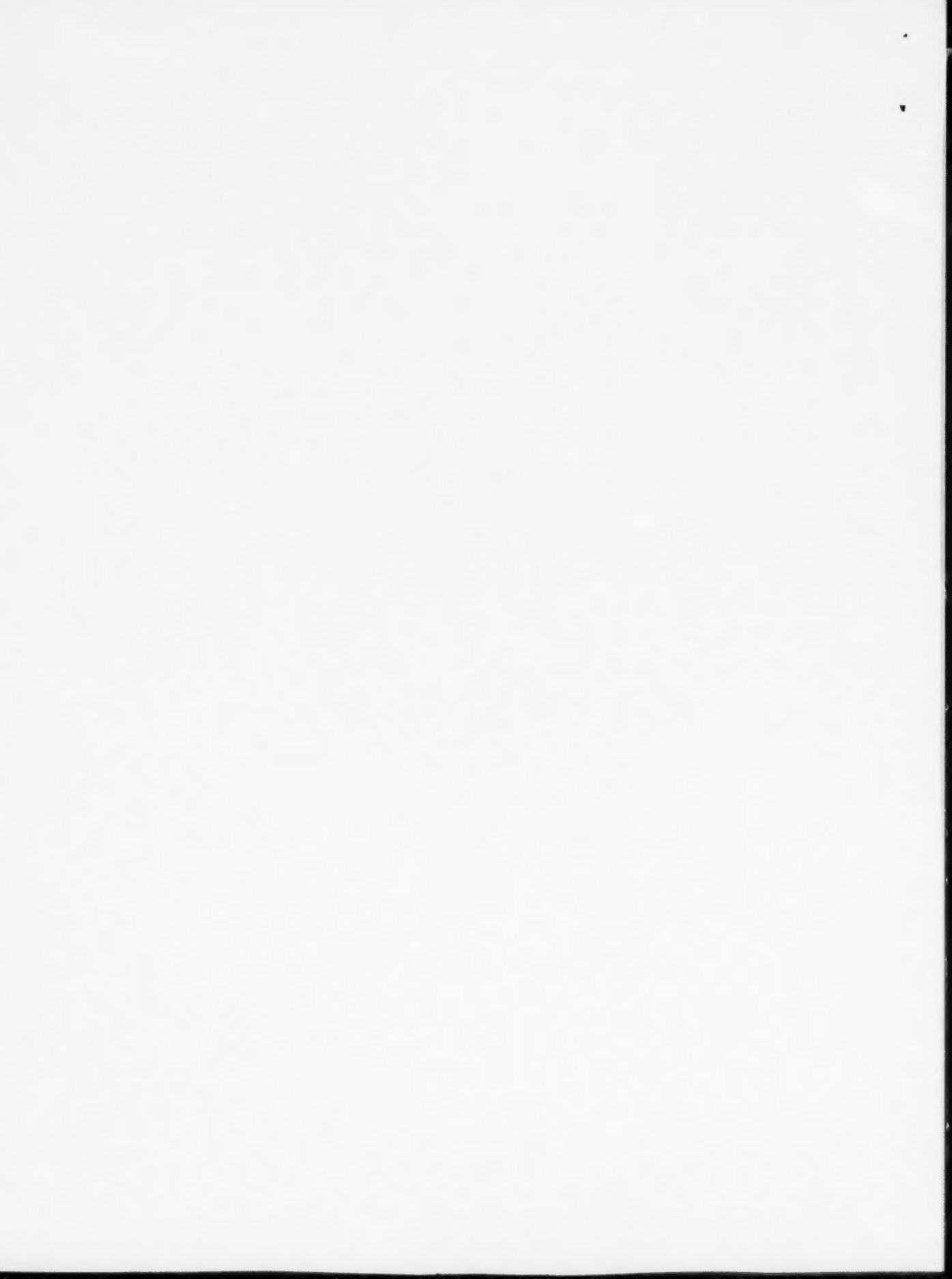
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Overview

Re-evaluation Decision

After a re-evaluation of the insect growth regulator S-methoprene, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing S-methoprene.

An evaluation of available scientific information found that products containing S-methoprene do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of S-methoprene uses, new risk-reduction measures must be included on the labels of products containing S-methoprene.

The regulatory approach for the re-evaluation of S-methoprene was first presented in Proposed Re-evaluation Document *PACR2007-01, Re-evaluation of S-methoprene*, a consultation document¹. This Re-evaluation Decision² describes this stage of PMRA's regulatory process for the re-evaluation of S-methoprene as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PACR2007-01. To comply with this decision, registrants of products containing S-methoprene will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive *DIR2001-03, PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

S-methoprene, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under the Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a regulatory decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated S-methoprene and published its conclusions in a 1991 RED document for methoprene; a 1991 methoprene RED Fact Sheet; a June 2001 updated methoprene RED Fact Sheet; and in the Inert Ingredient Focus Group Decision Document on Tolerance Reassessment for Methoprene published in August 2002. In addition to the USEPA documents, the PMRA environmental assessment used information from the United Kingdom (UK) Advisory Committee on Pesticides, the New Zealand Report for the Ministry of Health, published literature and toxicology websites.

What is S-methoprene?

S-methoprene is an insect growth regulator used to reduce the emergence of adult sciarid flies in mushroom cultures, to control fleas and ticks on dogs, cats and indoor premises, and to prevent the emergence of adult mosquitoes from standing water including flood water sites, permanent water sites, storm drain ditches and roadside ditches. Appendix II lists all products containing S-methoprene that are registered under the authority of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of S-methoprene Affect Human Health?

S-methoprene is unlikely to affect your health when used according to the revised label directions.

People could be exposed to S-methoprene through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that S-methoprene was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

S-methoprene is currently registered in Canada for use on mushrooms and could be used in other countries on crops that are imported into Canada. An MRL of 0.05 parts per million (ppm) has been established for S-methoprene on mushrooms in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When S-methoprene is Introduced Into the Environment?

S-methoprene is unlikely to affect non-target organisms when used according to the revised label directions.

Aquatic non-target organisms could be exposed to S-methoprene in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered as a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The use of S-methoprene as an insect growth regulator to prevent adult mosquito emergence does not pose an unacceptable risk to non-target aquatic organisms provided the risk-reduction measures to further protect the environment listed in Appendix III are implemented.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of S-methoprene, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixer/loader/applicators

Environment

- Additional label statements to protect non-target aquatic organisms

Appendix III lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection³ regarding this decision on S-methoprene within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmr-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

³ As per subsection 35(1) of the *Pest Control Products Act*.

List of Abbreviations

µg	microgram
a.i.	active ingredient
bw	body weight
cm	centimetre(s)
d	day(s)
DACO	data code
DT ₅₀	dissipation time to 50%
EEC	expected environmental concentration
EP	end-use product
g	gram(s)
h	hour(s)
ha	hectare
kg	kilogram(s)
L	litre(s)
LC ₅₀	lethal concentration to 50%
LD ₅₀	lethal dose to 50%
m	metre(s)
m ³	metre(s) cubed
min	minute(s)
mg	milligram(s)
mm	millimetre(s)
MRL	maximum residue limit
PACR	Proposed Acceptability for Continuing Registration
PCPA	<i>Pest Control Product Act</i>
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RED	Reregistration Eligibility Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Comments and Responses

1.0 Comment on NIOSH/MSHA-approved respirator requirement

In the published PACR2007-01, the following label statement was required on restricted end-use products formulated as granules and pellets:

“Wear a NIOSH/MSHA-approved respirator during mixing/loading, clean-up and repair activities.”

Further explanation is required on why a NIOSH/MSHA-approved respirator should be worn during mixing/loading, clean-up and repair activities when handling restricted use products formulated as granules and pellets. The EPA considers methoprene to pose no risks to people who are occupationally exposed to this biopesticide.

Response

The restricted use end-use products containing S-methoprene and formulated as granules and pellets are registered to be applied by ground equipment or by fixed wing or rotary aircraft equipment. On the current end-use product labels, the field crew and the loaders are instructed to wear chemical resistant gloves, coveralls and goggles or face shield during loading, cleanup and repair. In addition, in the PRECAUTIONS section, the use of a mask/respirator when transferring bulk product is strongly recommended.

The PMRA continues to recommend the use of a mask/respirator when transferring bulk product in order to reduce inhalation exposure. However, the PMRA agrees that the statement required in PACR2007-01 and the reason for it are not clear and therefore the statement has been modified as follows:

For restricted end-use products formulated as granules and pellets that are applied by ground equipment or by fixed wing or rotary aircraft, the statement in the **PRECAUTIONS** section of the label reading “The use of a mask/respirator when transferring bulk product is strongly recommended” must be updated to read:

- “The use of a dust mask or NIOSH/MSHA/BHSE-approved respirator with a suitable dust filter to reduce inhalation exposure when transferring bulk product is strongly recommended.”

2.0 Comment on maximum residue limits

It is recommended that the MRL for S-methoprene be confirmed. In PACR2007-01 it was stated that maximum residue limits (MRLs) of S-methoprene and its metabolites must not exceed 0.1 ppm. However, according to SOR/2004-47 23 March 2004 a Regulation amending the Food and Drug Regulation was made to Table II Division 15 of Part B Item M.6.1 to change the MRL for S-methoprene on mushrooms from 0.1 ppm to 0.05 ppm.

Response

The MRL of S-methoprene on mushrooms in Canada is 0.05 ppm.

3.0 Comment on "TOXIC to aquatic organisms" statement

The statement "TOXIC to aquatic organisms" should not be required on labels, or the statement should be revised to state what methoprene is toxic to, eg. "Toxic to some aquatic organisms such as ..."

Response

It is PMRA policy that if the acute median lethal concentration (LC_{50}) for a surrogate species of aquatic organisms tested, including algae, aquatic vascular plants, aquatic invertebrates, or fish is ≤ 1 mg/L (highly to very highly toxic according to the EPA aquatic hazard classification scheme), the label statement "TOXIC to aquatic organisms" is required on all labels of products containing the product. Methoprene LC_{50} s for *Daphnia magna* range from 0.002 to 0.09 mg a.i./L. In diving beetles, aquatic sowbugs, backswimmers and water boatmen, the LC_{50} range from 0.03 to 0.2 mg a.i./L. LC_{50} s in bluegill sunfish range from 0.105 to 4.4 mg a.i./L and in rainbow trout range from 0.44 to 106 mg a.i./L.

The label statement "TOXIC to aquatic organisms" reflects the inherent toxicity of methoprene and not the risk assessment. The statement is required for all pesticides that meet the LC_{50} criterion, as explained above. The PMRA requires the statement for the protection of non-target aquatic species, to ensure that the user understands that the product could be toxic to non-target species if used incorrectly.

4.0 Comment on removing environmental hazard statements

The label statements "Do not use in fish-bearing waters" and "This product is toxic to aquatic invertebrates" were removed from the product labels in the U.S. in 1996. Two documents were submitted to the PMRA on 26 August 2005, providing further information as to how the USEPA reached its decision to remove the aquatic hazard statements from the labels.

Response

Canadian labels do not contain the statement "do not use in fish-bearing waters".

In respect to the second label statement "This product is toxic to aquatic invertebrates", the registrant submitted the two documents after the PMRA had completed the environmental re-evaluation of methoprene. This information would not have changed the outcome of the risk assessment. The PMRA estimated methoprene concentrations as 5 to 14 μ g a.i./L, whereas one of the documents (Ross et al (1994)) found that concentrations of methoprene in mesocosms ranged from 0.12 to 0.24 μ g a.i./L. While this is true, using the refined estimated environmental concentration (EECs) estimated by the PMRA for methoprene (5 to 14 μ g a.i./L), the PMRA found that the risk was **negligible** (risk quotients were <1) for all aquatic organisms tested. Therefore, the PMRA

is not assigning risk to aquatic organisms with the estimated EECs. Even if the PMRA used the concentrations of methoprene observed by Ross et al. (1994), risk quotients would still be classified as “**negligible**”. However, this does not imply that methoprene is non-toxic to aquatic organisms, only that it does not pose a risk to aquatic organisms when used according to label directions. Because methoprene is used and marketed as a product that controls mosquito populations (through prevention of emergence), it therefore shows that it has adverse effects and disrupts the mosquito life cycle and previous data show that it is toxic to other aquatic biota as well.

5.0 Comment on Altosid XR Briquets label statement

It was recommended that the revised label statement:

“Apply Altosid XR briquets early in the mosquito season, when larvae start to develop. The limit is one application per season, unless briquets have been flushed away.”

be further revised to:

“Apply Altosid XR briquets early in the mosquito season when larvae start to develop. The limit is one application per season to reduce the amount of methoprene added to the environment. It is recommended that monitoring of pupal emergence rates be used to determine if further applications are required due to briquets that have been flushed away”.

Response

There is no need to further revise the label statement. If a briquet is flushed away, there would be a need for it to be replaced to ensure continued protection against emergence of adult mosquitoes.

6.0 Comment on calculation of EECs

Were the EECs calculated for pellets and briquets taking into consideration the differences in percent active ingredient in the two products?

Response

The differences in percent active ingredient of the products were taken into consideration. With regard to the briquets, which were 2.1% active ingredient, the label indicated that the net dry weight of 220 briquets was 8 kg. The maximum EEC for the briquets was calculated for the catch basin that would potentially reach the highest concentration. This was the 5501 L basin where two briquets were applied, based on the application rate indicated on the label. Two briquets will contain 1.512 g a.i. methoprene.

The following steps detail the calculation for the EEC in a 30 cm water body:

Instant release of 2 briquets (1.512 g a.i. methoprene) into 5501 L (label application rate):
= 0.2749 mg a.i./L

Approximate effective days:
= 150 (USEPA Registered Label)

Daily application rate: 0.2749 mg a.i./L/150 days
= daily application rate of 0.00183 mg a.i./L

Volume of water in 1 ha \times 30 cm deep basin = 100 m \times 100 m \times 0.30 m depth
= 3000 m³ \times 1000 L/m³ = 3 000 000 L water in 1 ha of water 30 cm deep

therefore: 0.00183 mg a.i./L \times 3 000 000 L (or 1 ha) = 5490 mg a.i./ha or 5.49 g a.i./ha

Cumulative Application Rate calculation:

Using 5.49 g a.i./ha as the application rate for the Cumulative Application Rate calculation with 150 days applied, 1 day interval between applications and $t_{1/2}$ of 1.46 d:

= cumulative application rate of 14.526 g a.i./ha

Standard PMRA calculation of EEC:

Using 14.526 g a.i./ha as the application rate for PMRA's standard EEC calculations into a body of water 30 cm deep
= 0.004842 mg a.i./L

The refined risk assessment for the granular and pellet formulations was conducted in the same manner as for briquet formulation where the potential dose of each (taking into consideration the percent active ingredient) was divided by the proposed number of days the granular or pellets were effective. This daily application rate was then used to determine a cumulative application rate for the effective period taking into consideration the $t_{1/2}$ of 1.46 d. The EECs were then calculated in the PMRA standard scenario water body of 30 cm depth and takes into consideration the full range of application rates (kg/ha) and the percent active ingredient present in each of the registered products.

7.0 Comment on recently registered end-use product

It was recommended that the recently registered Domestic class product, registration number 28152, be included in the re-evaluation.

Response

Four end-use products (registration nos. 25381, 25382, 25499 and 25500) were recently re-instated and seven end-use products (registration nos. 28070, 28152, 28199, 28360, 28382, 28598 and 28599) were newly registered between 2 August 2005 and 6 June 2007 and not included in PACR2007-01. However, these end-use products are included as part of this Decision document and the relevant label requirements in Appendix III also apply to these end-use products.

8.0 Comment on water monitoring data requirement

Two references (Struger et al. 2005 and Johnson and Kinney 2006) provide the additional data on water monitoring requirements that were deemed necessary in the re-evaluation of methoprene.

Response

It is recommended that the registrant submit these studies to the PMRA for evaluation. At that time the PMRA will be in a position to determine if they provide sufficient information for our needs.

9.0 Comment on referenced document

The research on lobster deaths in Long Island Sound was published in Vol 24, No. 3 in 2005, yet the methoprene re-evaluation document stated it was unpublished.

Response

The PMRA concurs that the research on lobster deaths in Long Island Sound was published and the complete reference is as follows:

Anthony Calabrese, Nancy Balcom, Antoinette Clemetson (guest editors). 2005. Contributions to the Long Island Sound Lobster Research Initiative. *J. Shellfish Research*. 24:3 687-875.

10.0 Comment on further recommendations for products containing S-methoprene

The Ontario Ministry of the Environment recommended that registrants be directed to provide information on rearing mosquito pupae to determine if further applications are necessary and that registrants also provide information that after rainy seasons or after a large rainstorm that a number of catch basins be sampled and pupae reared to determine if re-application is necessary.

Response

Training and licensing of applicators is under provincial jurisdiction. In view of the "Restricted" classification, a provincial permit is required. Suggestions from the province could be provided to the applicators at the time the permit is issued.

Appendix II Current Canadian Registered Products Containing S-methoprene as of 8 August 2007

Product Name	Registrant	Registration Number	Guarantee (% a.i.)	Marketing Class
Apex EC Insect Growth Regulator	Wellmark International	17247	(S)-Methoprene = 67	Commercial
Precor Insect Growth Regulator	Wellmark International	21191	(S)-Methoprene = 94.0	Technical active
Vet-Kem Ovitrol Plus for dogs and cats (with Precor)	Wellmark International	21206	(S)-Methoprene = 0.27 Pyrethrins = 0.20 Piperonyl butoxide, technical=0.37 N-octyl bicycloheptene dicarboximide = 0.62	Domestic
Vet-Kem Siphotrol P.M. (kills fleas)	Wellmark International	21357	(S)-Methoprene = 0.015 Pyrethrins = 0.20 Piperonyl butoxide, technical = 1.0 N-octyl bicycloheptene dicarboximide = 1.0	Domestic
Precor EC Emulsifiable Concentrate	Wellmark International	21573	(S)-Methoprene = 1.2	Commercial
Zodiac Flea & Tick Spray for Dogs and Cats	Wellmark International	21744	(S)-Methoprene = 0.27 Pyrethrins = 0.20 Piperonyl butoxide, technical = 0.37 N-octyl bicycloheptene dicarboximide = 0.62	Domestic
Zodiac Household Flea Spray	Wellmark International	21761	(S)-Methoprene = 0.015 Pyrethrins = 0.20 Piperonyl butoxide, technical = 1.0 N-octyl bicycloheptene dicarboximide = 1.0	Domestic
Altosid Pellets Mosquito Growth Regulator	Wellmark International	21809	(S)-Methoprene = 4.25	Restricted
Vet-Kem Siphotrol Forte Double Action	Wellmark International	22213	(S)-Methoprene = 0.01 Permethrin = 0.25	Domestic
Altosid Granules	Wellmark International	22676	(S)-Methoprene 1.5	Restricted
Vet-Kem Ovitrol Mousse for Cats and Dogs	Wellmark International	22678	(S)-Methoprene = 0.5 Pyrethrin = 0.4 Piperonyl Butoxide = 4.0	Domestic

Product Name	Registrant	Registration Number	Guarantee (% a.i.)	Marketing Class
Zodiac Mousse Flea & Tick Control for Cats and Dogs	Wellmark International	22916	(S)-Methoprene = 0.5 Pyrethrins = 0.4 Piperonyl Butoxide = 4.0	Domestic
Zodiac Premise Plus Flea Spray	Wellmark International	23075	(S)-Methoprene = 0.01 Permethrin = 0.25	Domestic
Vet-Kem Ovicollar for Cats	Wellmark International	23120	(S)-Methoprene = 2.1	Domestic
Vet-Kem Ovicollar for Dogs	Wellmark International	23121	(S)-Methoprene = 1.0	Domestic
Ovex Pump Spray for Dogs and Cats	Wellmark International	23692	(S)-Methoprene = 0.10 Pyrethrins = 0.20 Pieronyl butoxide, technical = 0.37 N-octyl bicycloheptene dicarboximide = 0.62	Domestic
Zodiac Flea Egg Collar for Cats	Wellmark International	23852	(S)-Methoprene = 2.1	Domestic
Zodiac Flea Egg Collar for Dogs	Wellmark International	23853	(S)-Methoprene = 1.0	Domestic
Raid Flea Killer Plus Dog Spray 1	S.C. Johnson & Son Ltd.	24320	(S)-Methoprene = 0.10 Pyrethrins = 0.18 Pieronyl butoxide, technical = 0.36 N-octyl bicycloheptene dicarboximide = 0.60	Domestic
Raid Flea Killer Plus Carpet & Room Spray	S.C. Johnson & Son Ltd.	24580	(S)-Methoprene = 0.015 Pyrethrins = 0.14 Piperonyl butoxide, technical = 1.0 N-octyl bicycloheptene dicarboximide = 1.0 Tetramethrin = 0.064	Domestic
Raid Flea Killer Plus 2 Pressurized Spray	S.C. Johnson & Son Ltd.	24581	(S)-Methoprene = 0.015 Pyrethrins = 0.14 Piperonyl butoxide, technical = 1.0 Tetramethrin = 0.064	Domestic
Hartz Control Pet Care System Flea & Tick Killer for Dogs	Hartz Canada Inc.	24650	(S)-Methoprene = 0.10 Pyrethrins = 0.18 Piperonyl Butoxide Technical = 0.36 N-octyl bicycloheptene dicarboximide = 0.60	Domestic
Hartz Control Pet Care System Home Flea & Tick Killer	Hartz Canada Inc.	24653	(S)-Methoprene = 0.007 Permethrin = 0.25	Domestic

Product Name	Registrant	Registration Number	Guarantee (% a.i.)	Marketing Class
Hartz Control Pet Care System Ultimate Flea Collar For Cats	Hartz Canada Inc.	25381	(S)-Methoprene = 1.02 Tetrachlorvinphos = 14.55	Domestic
Hartz Control Pet Care System Ultimate Flea Collar For Dogs	Hartz Canada Inc.	25382	(S)-Methoprene = 1.02 Tetrachlorvinphos = 14.55	Domestic
Hartz Control Pet Care System Ultimate Flea Collar For Puppies	Hartz Canada Inc.	25499	(S)-Methoprene = 1.02 Tetrachlorvinphos = 14.55	Domestic
Hartz Control Pet Care System Ultimate Flea Collar For Cats - Safety Snap Button	Hartz Canada Inc.	25500	(S)-Methoprene = 1.02 Tetrachlorvinphos = 14.55	Domestic
Zodiac Power Band Dual Action Flea & Tick Collar for Cats	Wellmark International	25568*	(S)-Methoprene = 1.02 Tetrachlorvinphos = 14.55	Domestic
Zodiac Power Band Dual Action Flea & Tick Collar for Dogs	Wellmark International	25569*	(S)-Methoprene = 1.02 Tetrachlorvinphos = 14.55	Domestic
Vet-Kem Siphotrol 2000 Double Action Premise Treatment	Wellmark International	25582	(S)-Methoprene = 0.078 Permethrin = 0.80	Domestic
Zodiac Premise 2000 Flea Spray	Wellmark International	25695	(S)-Methoprene = 0.078 Permethrin = 0.80	Domestic
Zodiac Premise 1000 Flea Spray	Wellmark International	25738	(S)-Methoprene = 0.078 Permethrin = 0.80	Domestic
Vet-Kem Siphotrol 1000 Double Action Premise Treatment	Wellmark International	25739	(S)-Methoprene = 0.078 Permethrin = 0.80	Domestic
Hartz Control Pet Care System One Spot - Master	Hartz Canada Inc.	26239	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Hartz Reference 114 (One Spot) for Cats and Kittens	Hartz Canada Inc.	26255	(S)-Methoprene = 2.9	Domestic

Product Name	Registrant	Registration Number	Guarantee (% a.i.)	Marketing Class
Zodiac Double Action Flea & Tick Shampoo for Dogs and Cats	Wellmark International	26413	(S)-Methoprene = 0.1 Pyrethrins = 0.15 Piperonyl Butoxide = 1.50	Domestic
Hartz Control Pet Care System One Spot for Dogs and Puppies 14 kg and Under	Hartz Canada Inc.	26489	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Hartz Control Pet Care System One Spot for Dogs and Pups over 14 Kg	Hartz Canada Inc.	26490	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Hartz Control Pet Care System One Spot Flea Topical Treatment for Cats and Kittens	Hartz Canada Inc.	26491	(S)-Methoprene = 2.9	Domestic
Vet-Kem Ovispot Plus Flea & Tick Control for Dogs Under 14 kg	Wellmark International	26492	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Zodiac Powerspot Flea & Tick Control for Dogs Over 14 kg	Wellmark International	26493	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Zodiac Powerspot Flea & Tick Control for Dogs Under 14 kg	Wellmark International	26494	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Vet Kem Ovispot plus Flea & Tick Control for Dogs over 14 kg	Wellmark International	26495	(S)-Methoprene = 2.9 Permethrin = 45	Domestic
Zodiac Spot on Flea Control for Cats and Kittens	Wellmark International	26496	(S)-Methoprene = 2.9	Domestic
Vet-Kem Ovispot Flea Control for Cats and Kittens	Wellmark International	26497	(S)-Methoprene = 2.9	Domestic

Product Name	Registrant	Registration Number	Guarantee (% a.i.)	Marketing Class
Vet-Kem Ovitrol plus Flea & Tick Shampoo for Dogs and Cats	Wellmark International	26608	(S)-Methoprene = 0.1 Pyrethrins = 0.15 Piperonyl Butoxide = 1.50	Domestic
Apex EC	Wellmark International	27473	(S)-Methoprene = 33.6	Commercial
Altosid XR Briquets	Wellmark International	27694**	(S)-Methoprene = 2.1	Restricted
Altosid Liquid Larvicide	Wellmark International	28070	(S)-Methoprene = 20.0	Restricted
Pre-Strike	Wellmark International	28152	(S)-Methoprene = 1.5	Domestic
Zodiac Powerband Plus Double Action Flea & Tick Collar for Cats & Kittens	Wellmark International	28199	(S)-Methoprene = 2.1 Propoxur = 10.0	Domestic
Zodiac Powerband Plus Double Action Flea & Tick Collar for Dogs and Puppies	Wellmark International	28360	(S)-Methoprene = 2.1 Propoxur = 10.0	Domestic
Zodiac Dual Action Flea & Tick Spray for Cats & Kittens	Wellmark International	28382	(S)-Methoprene = 0.27 N-octyl Bicycloheptene Dicarboximide = 0.62 Pyrethrins = 0.20 Piperonyl Butoxide = 0.37	Domestic
Vet Kem Ovitrol Dual Action Collar for Cats & Kittens	Wellmark International	28598	(S)-Methoprene = 2.1 Propoxur = 10.0	Domestic
Vet Kem Ovitrol Dual Action Collar for Dogs & Puppies	Wellmark International	28599	(S)-Methoprene = 2.1 Propoxur = 10.0	Domestic

* Zodiac Power Band Dual Action Flea & Tick Collar for Cats (Registration No. 25568) and Zodiac Power Band Dual Action Flea & Tick Collar for Dogs (Registration No. 25569) are no longer manufactured, but existing stocks can be used until 27 February 2008, and 6 October 2007, respectively.

** Altosid XR Briquets (Registration No. 27694) has been granted a conditional registration until 31 December 2008.

Appendix III Label Amendments for Products Containing S-methoprene

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

Canadian Regulatory Actions Relating to Human Health

1. For all domestic end-use products registered for use on cats and dogs, labels must comply with the PMRA's current requirements as specified in Regulatory Directive DIR2002-01, *Canadian Label Improvement Program for Pesticides Used on Companion Animals*.
2. For commercial end-use products used on mushrooms, the following statement must be added to a section entitled **PRECAUTIONS**:
 - Wear chemical resistant gloves when handling and/or applying this product.
3. For restricted end-use products, the following statement must be added to a section entitled **PRECAUTIONS**:
 - Wear chemical resistant gloves when handling and/or applying this product.
4. For restricted end-use products formulated as granules and pellets that are applied by ground equipment or by fixed wing or rotary aircraft, the statement in the **PRECAUTIONS** section of the label reading "The use of a mask/respirator when transferring bulk product is strongly recommended" must be updated to read:
 - The use of a dust mask or NIOSH/MSHA/BHSE-approved respirator with a suitable dust filter to reduce inhalation exposure when transferring bulk product is strongly recommended.

Proposed Regulatory Actions Relating to Environment

1. For all products that are applied directly to water (i.e. all Altosid formulations) and for Apex EC Insect Growth Regulator (Reg. No. 17247), the following statement must be added to a section entitled **ENVIRONMENTAL HAZARDS**:
 - TOXIC to aquatic organisms.
2. For Altosid XR Briquets (Reg. No. 27694) change the following label statements in the section entitled **DIRECTIONS FOR USE**:
 - a) • From: "Apply ALTOSID XR BRIQUETS early in the mosquito season, when larvae start to develop. Monitor larval populations to determine if and when further applications are required."

- To: "Apply ALTOSID XR BRIQUETS early in the mosquito season, when larvae start to develop. The limit is one application per season, unless briquets have been flushed away."
- b)
 - From: "Large water flows may accelerate the dissolution of the briquet. Monitor larval populations to determine if and when further applications are required."
 - To: "Large water flows may accelerate the dissolution of the briquet. The limit is one application per season, unless briquets have been flushed or dissolved away."
- 3. For Apex EC Insect Growth Regulator (Reg. No. 17247), the following statement must be added to a section entitled **DIRECTIONS FOR USE**:
 - DO NOT allow effluent or runoff from greenhouses or mushroom houses containing this product to enter lakes, streams, ponds or other waters.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.